AUG 2 2 2000

EXHIBIT # 1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K000969

1. Submitter's Identification:

Microlife Corporation
9F, 431 Rui Guang Road
Nei Hu,
Taipei 114
Taiwan, Republic of China

Contact:

Mr. Dawkins Liu

Date Summary Prepared: March 2000

2. Name of the Device:

Microlife Digital Infrared Ear Thermometer, Model IR1DA1.

3. Predicate Device Information:

1. Braun ThermoScan® Instant Thermometer, (Model 3020/3520) K# 902912, K# 930680, K# 954523 and K# 964605, ThermoScan Inc.

2. B-D Assure Ear Thermometer, K# 991994, Becton Dickinson Consumer Products, Franklin Lakes, NJ

4. Device Description:

The Microlife Digital Infrared Ear Thermometer, Model IR1DA1 is an electronic thermometer using an infrared sensor (thermopile) to detect body temperature from the auditory canal. Its operation is based on measuring the natural thermal radiation emanating from the tympanic membrane and the adjacent surfaces.

The Microlife Digital Infrared Ear Thermometer, consists mainly of five parts:

a) IR Thermopile Sensor
b) ASIC
c) E^2 PROM IC
d) LCD and Blacklight
e) Key *2, Buzzer *1

5. Intended Use:

The device is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

6. Comparison to Predicate Devices:

The Microlife Digital Infrared Ear Thermometer, Model IR1DA1 is substantially equivalent to the following infrared ear thermometers:

- Braun ThermoScan® Instant Thermometer, K# 902912, K# 930680, K# 954523 and K# 964605, ThermoScan Inc. (Models IRT 3020 and IRT 3520),

- B-D Assure Ear Thermometer, K# 991994, Becton Dickinson Consumer Products, Franklin Lakes, NJ

The Microlife Infrared Thermometer is similar in design and intended use to the predicates differing only in the probe assembly construction for the Braun ThermoScan®, and, normal mode vs. rock mode between the two predicates. The B-D Assure device works with a "rock" mode or 3-second mode. The Microlife device works with both a 1-second (as with the Braun ThermoScan®) called a "normal" mode, as well as a 3-second "rock" mode. The basic feature of the 3-second mode is that the unit will find the temperature peak value in the ear canal.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ASTM E1112, ASTM E1104 and ASTM E-1965-98, as well as IEC 60601-1 and IEC 60601-1-2 requirements.

Guidance Documents included the "FDA Guidance On The Content of Premarket Notification (510(k)) Submissions for Clinical Electronic Thermometers".

8. Discussion of Clinical Tests Performed:

Controlled human clinical studies were conducted using the Microlife Digital Infrared Ear Thermometer. Clinical data is presented evaluating clinical bias, uncertainty and clinical repeatability (both normal and rock modes) per ASTM E-1965-98. The patient population is well represented (neonatal, pediatrics and adults), and the number of patients have been statistically justified.

9. Conclusions:

The Microlife Digital Infrared Ear Thermometer, Model IR1DA1 has the same intended use and similar technological characteristics as the Braun ThermoScan® Instant Thermometer and B-D Assure Ear Thermometer devices. Moreover, bench testing contained in this submission and clinical testing supplied demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Microlife Digital Infrared Ear Thermometer, Model IR1DA1 is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 22 2000

Microlife Corporation
C/O Ms. Susan D. Goldstein-Falk
Official Correspondent
MDI Consultants, Incorporated
55 Northern Boulevard Suite 200
Great Neck, New York 11021

Re: K000969
Trade Name: MicroLife Digital Infrared Thermometer, Model IR1DA1
Regulatory Class: II
Product Code: FLL
Dated: June 21, 2000
Received: June 23, 2000

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center of Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K 000 969

Device Name: MicroLife Digital Infrared Ear Thermometer, Model IR1DA1

Indications For Use:

The device is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ **(Per 21 CFR 801.109)** **OR** **Over-The-Counter Use** X **(Optional Format 1-2-96)**

Rebecca Cucenda

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K000969